

**REMARKS**

Applicants would like to thank the Examiner for the teleconference of December 4, 2002 with Applicants' attorney, Johnney Han, during which time the claims were discussed. Currently claims 1-97 are pending in the present application. Claims 1, 47, and 76 have been amended. Accordingly, claims 1-97 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any subject matter of the claims as previously presented.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

**Objection to Informalities in the Specification**

The Office has objected to the disclosure because of alleged informalities in the **Brief Description of the Drawings** as failing to provide description for Figs. 33 (A, B); Figs. 34 (A, B); Figs. 35 (A, B); and Figs. 36 (A, B).

Applicants note that the relevant description currently recites "FIGS. 32A-36B show top and side views of alternative variations on the clip" in the **Brief Description of the Drawings**. Applicants contend that such recitation is explicitly inclusive of all figures beginning from FIG. 32A and ending with FIG. 36B, i.e., 32 (A, B); 33 (A, B); 34 (A, B); 35 (A, B); and 36 (A, B), under 37 CFR §1.74 and MPEP 608.01(f). Moreover, the use of a dash, i.e., "-", is generally known to indicate and include the range of figures noted.

Accordingly, Applicants submit that no correction is required and that the objection to the specification be withdrawn.

**Rejections Under 35 U.S.C. § 102(b)**

A. The Office has rejected claims 1-5, 7-12, 15, 18, 22, 24, 25, 28-36, 38, 40, 41, 47-49, 51, 52, 55-60, 63-68, 75-82, 84, 91, and 94-97 as allegedly being anticipated by Cohen (U.S. Pat. No. 5,336,252).

In support of the rejection of claims 1-5, 7-12, 15, 18, 22, 24, 25, 28-36, 38, 40, 41, 47-49, 51, 52, 55-60, 63-68, 75-82, 84, 91, and 94-97, the Office Action (Paper No. 9) states the following on pages 3-4:

As to claims 1-5, 47-49 and 76-78, Cohen discloses a device and methods for modifying the flow through the cardiac valve, the device comprising a guide catheter for delivering a cinching member having a central region 148 and at least two opposing anchoring regions 150 to the cardiac tissue 109. In regard to claims 76-78, the electrode 142 (lead wire) of Cohen would, and therefore the anchoring regions 42 induce thermal shrinkage of collagen in the tissue, thereby modifying flow through the heart valves. See Figures 20-2; Col. 4, line 66- Col. 5, line 26; and Col. 14, lines 37-41.

As to claims 7, 8, 18, 22, 38, 51, 52, 84, he teaches that the electrode 142, and therefore the anchoring regions 150, are substantially coated with a biocompatible insulator 144, such as polyurethane or silicone (Col. 14, lines 35-37). In reference to claim 22 and 38, the coating material of Cohen, which is selected from the group consisting of polyurethane or silicone, is treated to be radiopaque to certain forms of radiation.

As to claims 9-11, 28-33, 56, 58, 59 and 94-97, he discloses fixation/anchoring means selected from the group consisting of crimping or adhesive bonding (Col. 14, lines 41-45); V-shapes (Fig. 22); and jaws, hooks or pivoting (Figs. 3 and 18). In regards to claim 29, the anchoring regions and configured to pierce the tissue.

As to claims 34-26 and 66-68, he further discloses a stylet 108 (guide wire) with a hooked distal tip 110 disposed at the distal end of the device, the stylet being slightly disposed in the catheter lumen and being manipulated from its proximal end. See Fig. 18; Col. 13, lines 16-28; and claim 1 of Cohen. In reference to claims 80-82, his device would provide the methods as presently claimed.

In response, independent claims 1 and 76 have been amended to recite "wherein each anchoring region is configured to be anchored to opposing areas of tissue and urge the areas of tissue towards one another". Independent claim 47 has been amended to similarly recite "such that the first area and the second area are urged towards one another by the cinching member". (Support is found throughout the specification as filed, particularly [0115].)

Cohen, however, describes a device for inducing defibrillation shock which is placed within the pericardial space 109 and not within the heart tissue. The device of Cohen is clearly shown and described (Cohen, 14: 48-54; Fig. 22) as an end cap 146 having barbs 150 which are designed to "resist withdrawal of the end cap 146 back out of the hole." On the other hand, independent claims 1, 47, and 76 all recite cinching members which are "anchored to opposing areas of tissue and urge the areas of tissue towards one another". Cohen therefore fails to show or describe a device which is configured to cinch or bring the edges of a valve towards one another but instead describes one which is only configured to prevent it from being pulled back through a hole.

Therefore, by law, Cohen cannot anticipate independent claims 1, 47, and 76. Dependent claims 2-5, 7-12, 15, 18, 22, 24, 25, 28-36, 38, 40, 41, 48-49, 51, 52, 55-60, 63-68, 75, 77-82, 84, 91, and 94-97 all depend ultimately from independent claims 1, 47, and 76 and are patentable over Cohen for at least the same reasons as above. Accordingly, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. § 102(b).

#### Rejections Under 35 U.S.C. § 103(a)

The Office has rejected claims 6, 13, 14, 16, 17, 19-21, 23, 26, 27, 37, 39, 42-46, 50, 53, 54, 61, 62, 69, 70-74, 83, 85-90, 92 and 93 as allegedly being unpatentable over Cohen variously in view of Muller (U.S. Pat. No. 5,725,521); Jeevanandam et al. (U.S. Pat. No. 5,957,916); Crowley et al. (U.S. Pat. No. 6,004,264); and Abrams (U.S. Pat. No. 5,492,119).

In support of the rejection of claims 37 and 69, the Office Action (Paper No. 9) states the following on page 4:

Although Cohen, described above, uses sliding mechanism to advance and retract the stylet (guide wire), he does not particularly teach its type. Muller teaches an alternative heart modifying device and methods comprising a thumb-slide advancing mechanism. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Cohen and Muller and use a thumb-slide as an alternative advancing mechanism.

In support of the rejection of claims 6, 13, 14, 26, 27, 50, 61, 62, 83, 85-88, 92 and 93, the Office Action (Paper No. 9) states the following on page 5:

Cohen, described above, do not teach a plurality of cinching/anchoring member wherein the separation angles between the anchoring members relative a central plane is about 60° to 120° as presently claimed. Jeevanandam et al. disclose a myocardial revascularization device and method for modifying flow through the heart, the device comprising a plurality of anchoring members 44. The separation angles between their anchoring members relative to a common central plane falls within a range of about 60° to 120° as presently claimed. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen in view of Jeevanandam et al. and use plurality of separated anchoring members in order to substantially secure the treatment device near the tissue being treated.

In support of the rejection of claims 19-21, 23, 39, 43-46, and 70-74, the Office Action (Paper No. 9) states the following on pages 5-6:

Cohen, described above, do not teach the use of therapeutic coating, radiopaque material selected from the group consisting of platinum, gold, etc., or an ultrasound sensor connected to a monitor for guiding the system as presently claimed.

However, Crowley et al. disclose an ultrasound guided catheter and method for modifying the flow through a cardiac valve, the device comprising: therapeutic agents; radiopaque markers; coating material selected from the group consisting of platinum and gold; and ultrasound sensor disposed at the tip of the catheter device for monitoring the treatment and operations of the device. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen with Crowley et al. to employ radiopaque markers and ultrasound sensors in order to monitor the operation of the system. It would have been obvious to one skilled in the art at the time of the applicant's invention to use gold or platinum as an alternative coating material.

In support of the rejection of claims 16, 17, 42, 53, 54, 89, and 90, the Office Action (Paper No. 9) states the following on page 6:

Although the hooked member 108 of Cohen conforms to a predetermined shape, he does not particularly teach his hooked member is made from a shape memory material. He further fails to describe the material in which it is made.

Abrams teaches an alternative medical catheter device comprising a biocompatible material selected from the group consisting of shape memory alloys, such as Nickel-Titanium alloy, for modify the flow through a heart valve. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Cohen in view of Abrams to use a cinching/anchoring member made from a shape memory material so as to have a cinching/anchoring member that conforms to a predetermined shape after it is deployed through the catheter.

Applicants respectfully disagree. Independent claims 1, 47, and 76 are patentable over Cohen for at least the same reasons as above and Muller, Jeevanandam et al., Crowley et al., and Abrams (or any other reference) necessarily fail to cure the defects of Cohen. Dependent claims 6, 13, 14, 16, 17, 19-21, 23, 26, 27, 37, 39, 42-46, 50, 53, 54, 61, 62, 69, 70-74, 83, 85-90, 92 and 93 all ultimately depend from independent claims 1, 47, and 76 and are patentable for at least the same reasons.

Accordingly, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. § 103(a).

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CONCLUSIONS

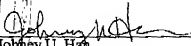
Applicants have, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no: 509192000220.

Respectfully submitted,

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